



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 26 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: PP's# 3F4309 / 3H5686: EPA Reg. No. 3125-351.
Cyfluthrin in/on Alfalfa, Sunflowers, Sweet Corn and
Soybeans. Evaluation of Analytical Methods and of
Residue Data. MRID Nos. 428646-01 thru -05. DP
Barcodes D198397 and 198399. CBTS Nos. 13093 and
13094.

FROM: Joel Garbus, PhD., Chemist *Joel Garbus*
Tolerance Petition Section III
Chemistry Branch Tolerance Support (7509c)

THROUGH: Edward Zager, Acting Chief *Edward Zager*
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TO: G. LaRocca / L. Arrington, PM-13
Registration Division (7505c)

Miles, Inc., Agriculture Division, Kansas City, MO, has petitioned to amend 40 CFR 180.436 to add permanent tolerances for the insecticide cyfluthrin, [cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate], in or on alfalfa forage at 5.0 ppm, alfalfa hay at 10 ppm, sweet corn at 0.05 ppm, sweet corn forage at 54.0 ppm, soybean, bean at 0.03 ppm, soybean forage at 10 ppm, soybean hay at 1.5 ppm, sunflower seed at 0.02 ppm, and sunflower forage at 1.0 ppm. The registrant has also petitioned to amend 40 CFR 186.1250 to add feed additive tolerances for soybean hulls at 0.1 ppm and for sunflower hulls at 0.05 ppm and to amend 40 CFR 185.1250 to add refined sunflower oil at 0.05 ppm.

These uses and associated tolerances were proposed originally in association with PP#9F3731, together with requested uses and tolerances for additional crops and increases in meat and milk tolerances due to potentially increased livestock burdens. CBTS' review (H. Fonouni, memo, 11/17/89) cited deficiencies in the data supporting the uses on alfalfa, sweet corn, soybeans, and sunflowers and consequently recommended against tolerances for these



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commodities. Subsequently, the petitioner withdrew its request for use on these commodities.

Specifically, in regard to these commodities, CBTS' review of PP#9F3731 requested:

- a) a revision of the label to prohibit aerial application
- b) prohibition of application to alfalfa grown for seed or the proposing of tolerances for alfalfa seed and screenings
- c) a PHI of 30 days for sunflower forage and a 15 day restriction on grazing soybeans
- d) storage stability studies for soybean rac's
- e) processing studies for soybeans and sunflowers

The current petition is a resubmission of the information supplied with PP#9F3731 with additional data to answer the deficiencies noted in CBTS' 1989 review.

Conclusions and Recommendations

1a. The deficiencies regarding the need for a PHI of 30 days for sunflower forage and the need for a 15 day restriction on grazing soybeans have been met by the proposed labeling.

1b. Restrictions against the feeding of alfalfa seeds or seed screenings to livestock are not considered practical unless issued under 24(c) registrations in states having an oversight program for these commodities. In the absence of such a program, data are required for seeds and seed screenings (see Conclusion 5a).

1c. The petitioner has responded to the deficiency regarding the need for a prohibition on aerial application due to the absence of residue data for this mode of application by referencing PR notice 93-2. This citation state that data from ground applications can be used to support aerial applications.

2. The Agency has determined that the residue of concern in/on plants and animal commodities is the parent, cyfluthrin.

3a. The analytical methods are adequate for enforcement purposes and for the generation of the field trial data.

3b. The storage stability data submitted with this petition in which samples of soybean rac's were for 194 days is adequate for this interval for this crop.

3c. Specific storage stability data for some of the crops and storage intervals in this petition have not been provided. However, the petitioner cites data from other studies that address the adequacy of the field trial data. (See conclusions 4c and 6b below)

These studies include data indicating that cyfluthrin and its metabolites are relatively stable over long term frozen storage (up to 35 months) in/on numerous other crops.

4a. The field trial residue data and the processing study procedure for arriving at residue levels in/on processed soybean commodities do not support the requested tolerances for soybean rac's and processed commodities.

4b. Although there are now a sufficient number and adequate geographic representation of soybean residue trials, the results cannot be reconciled with the requested tolerances. The maximum residue found on soybean forage was 3.3 ppm yet the requested tolerance is 10 ppm, and even though the maximum residue found on soybean hay was 3.2 ppm the petitioner has proposed a tolerance of 1.5 ppm, half the actual maximum residue.

4c. Soybean rac samples were stored for a maximum of 433 days in all of the submitted field trials, yet the storage stability study that the petitioner has submitted in response to a request for additional data reflected samples stored for a maximum of 194 days and as such is not appropriate. However, the storage stability studies with various crops and processed commodities when examined in toto demonstrate a lack of substantial degradation over of the interval of storage of these field trails. It is unlikely that the storage interval would have had any significant effect on the residue levels found with soybean rac's.

4d. The procedure used to arrive at values for residues and tolerances for processed soybean commodities is inappropriate. The petitioner has not provided an actual soybean processing study but instead relies upon a cottonseed processing study.

5a. The results of the additional residue trials with alfalfa forage and hay do not support the requested tolerances as samples were taken 7 days after the last application while the label allows for a 0 day PHI. Only one trial was conducted to support a tolerance request for alfalfa grown for seed; one trial is an insufficient number to support a tolerance. No additional storage stability data for alfalfa rac's have been provided.

5b. CBTS concludes that the alfalfa residue data currently available do not support the requested tolerances on alfalfa forage, hay, and alfalfa seed.

6a. CBTS accepts the results of the sunflower seed processing study as adequate but considers the proposed tolerances derived

from the study as inappropriate. The concentration factor of 1.1 found for sunflower refined oil and hulls is not significant and consequently food/feed additive tolerances for these commodities are not necessary. Although concentration was observed in crude oil, FAT's are not set on the crude oil. A revised Section F is needed.

6b. Sunflower rac's and processed commodities were stored a maximum of 440 days, considering this study and the previously submitted report of field trials conducted with sunflower rac's. The petitioner has not submitted any data for stored samples of sunflower rac's or processed commodities. However, the storage stability studies with various crops and processed commodities when examined in toto demonstrate a lack of substantial degradation over the interval of storage of the field trial and processing study. It is unlikely that the storage intervals of this study would have had any significant effect on the residue levels found.

7a. In regard to field trials with sweet corn, the petitioner has not responded to the specific deficiency cited in CBTS' review, i.e., the lack of storage stability data for corn rac's. The petitioner has not submitted any data for stored samples of sweet corn rac's or processed commodities.

7b. Instead the petitioner has cited Miles reports regarding the storage stability of cyfluthrin in various commodities which indicate a 2% decline in residues stored 783 days in corn green forage and of 6% in corn grain stored 201 days.

The storage stability studies with various crops and processed commodities when examined in toto demonstrate a lack of substantial degradation over the interval of storage of the field trail and processing study. It is unlikely that the storage interval would have had any significant effect on the residue levels found. Therefore, CBTS is willing to forego the issue of the storage stability of cyfluthrin in the specific crop sweet corn.

7c. The sweet corn forage should be lowered to 15 ppm. The sweet corn tolerances should be expressed in terms of kernel plus cob with husk removed (K+CWHR). In addition, a tolerance of 30 ppm is needed for sweet corn fodder.

8a. The commodities for which tolerances are proposed in this petition can be a substantial part of animal diets.

8b. From calculated potential residue levels in feed items and from calculated potential residue levels based on previously submitted feeding studies, it is evident that the establishment of the tolerances proposed in this petition would result in the need for increases in the tolerances for secondary residues in animal commodities, at least for fat of cattle, goats, hogs, horses, and sheep.

8c. Once the issue of the adequacy of the tolerances proposed for the commodities in this petition is resolved, the petitioner will need to propose adequate tolerances for secondary residues in animal commodities.

Recommendations

CBTS can recommend for the sunflower rac tolerance if the food/feed additive tolerances are deleted as suggested above. (Conclusion 6a)

The establishment of tolerances on sweet corn rac's (see Conclusion 7c) will require the revision of tolerances for secondary residues in animal commodities. (see Conclusions 8b, 8c)

In regard to soybeans, the petitioner should: a) request tolerances that reflect actual residue trial results, and b) conduct an actual soybean processing study. (Conclusions 4a, 4b, and 4d)

In regard to alfalfa, the petitioner should conduct additional trials on forage and hay reflecting the proposed PHI in geographically diverse areas to increase the number of acceptable trials to at least twelve. (See EPA document 738-K-94-001 for guidance in determining the number and location of domestic crop field trials.) Additional data will also be needed for alfalfa grown for seed and seed screenings. (Conclusions 1b, 5a and 5b)

Once the issue of the adequacy of the tolerances proposed for the commodities in this petition is resolved, the petitioner will need to propose adequate tolerances for secondary residues in animal commodities. (Conclusions 8b and 8c)

Product Chemistry

The product chemistry data requirements have been met for cyfluthrin.

Residue Chemistry

Use Pattern

Cyfluthrin is to be applied to the crops of this petition as Baythroid 2, an emulsifiable pyrethroid insecticide, consisting of 25% active ingredient, cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate.

Alfalfa (not grown for seed): Depending upon the nature and pressure of the insect pest, rates can be from 0.0125 to 0.044 lbs ai per acre, (0.8 to 2.8 fl. oz. of formulated material). Sufficient water (a minimum of 2 gallons for aerial applications) should be used to ensure thorough coverage of foliage. Baythroid

2 may be applied by air as an ULV application and, with oil, using ground equipment in a total volume of 1 quart per acre.

A total of 0.176 lbs ai (11.2 fl. oz) may be applied per season. There is no PHI. Applications are permitted up to and including the day of harvest.

Alfalfa (grown for seed): Depending upon the nature and pressure of the insect pest, rates can be from 0.025 to 0.044 lbs ai per acre, (1.6 to 2.8 fl. oz. of formulated material). Sufficient water (a minimum of 2 gallons for aerial applications) should be used to ensure thorough coverage of foliage. Two application can be made per season; one, prebloom, but no closer than 14 days prior to the introduction of bees, and a second after bees have been removed. Treated alfalfa seed and chaff is not to be used as animal food or feed. No PHI is indicated after the last treatment.

Soybeans: Depending upon the nature and pressure of the insect pest, rates can be from 0.025 to 0.044 lbs ai per acre, (1.6 to 2.8 fl. oz. of formulated material). Application by air or ground equipment should utilize sufficient water (a minimum of 4 gallons) to ensure thorough coverage of foliage. A total of 0.176 lbs ai (11.2 fl. oz) may be applied per season with an interval of at least 7 days between individual applications. A PHI of 45 days is imposed between the last application and harvest of soybeans and feeding of dry soybean vines. A PHI of 15 days is imposed for the feeding of green soybean forage.

Sweet Corn: Depending upon the nature and pressure of the insect pest, rates can be from 0.0125 to 0.044 lbs ai per acre, (0.8 to 2.8 fl. oz. of formulated material). Application by air or ground equipment should utilize sufficient water (a minimum of 3 gallons) to ensure thorough coverage of foliage. A total of 0.176 lbs ai (11.2 fl. oz) may be applied per season. Baythroid 2 may be applied by air as an ULV application and, with sprayable vegetable oil, using ground equipment in a total volume of 1 quart per acre. Applications for the control of cutworms should be as a broadcast or banded spray directed at the base of plants.

A total of 10 applications can be made per crop. A total 0.448 lbs ai (28 fl. oz) may be applied per season. There is no PHI. Applications are permitted up to and including the day of harvest.

Sunflowers: Depending upon the nature and pressure of the insect pest, rates can be from 0.0125 to 0.044 lbs ai per acre, (0.8 to 2.8 fl. oz. of formulated material). Application by air or ground equipment should utilize sufficient water (a minimum of 2 gallons) to ensure thorough coverage of foliage and heads. Baythroid 2 may be applied by chemigation, following the directions on the full label.

A total of 0.132 lbs ai (8.4 fl oz) may be applied per season with an interval of 7 days between applications. There is a PHI of 30 days between the last application and harvest. Forage is not to be fed or grazed within 30 days of application.

Comment and Conclusions

The deficiencies cited in CBTS's review of 11/17/89 regarding the need for a PHI of 30 days for sunflower forage and the need for a 15 day restriction on grazing soybeans have been met by the proposed labeling. These deficiencies are resolved.

Restrictions against the feeding of alfalfa seeds or seed screenings to livestock are not considered practical unless issued under 24(c) registrations in states having an oversight program for these commodities. In the absence of such a program, data are required for seeds and seed screenings (see Conclusion 5a).

The petitioner responded to the deficiency regarding the need for a prohibition on aerial application due to the absence of residue data for this mode of application by referencing PR notice 93-2 and a letter dated 12/6/91 from Robert Quick to Richard Holt. These citations state that data from ground applications can be used to support aerial applications. This deficiency is resolved.

Nature of the Residue in Plants and Animal Commodities

The Agency has determined that the residue of concern in/on plants and animal commodities is the parent, cyfluthrin.

Analytical methods

Adequate validated enforcement analytical methods are available for cyfluthrin and are published in PAM II.

Storage Stability

CBTS specifically asked for additional data regarding the storage stability of cyfluthrin in/on soybean rac's when considering the petitioner's initial request for tolerances in/on soybeans (Fonouni memo 11/17/89).

In response, the petitioner has submitted the results of a study conducted in 1984 in which samples of soybeans and dried soybean vines fortified with radioactive DCVA (Dichlorovinyl Acid) were stored for periods of 139 and 194 days. The matrices were solvent extracted and concentrated samples of the extracts subjected to thin layer chromatography. After autoradiography, the radioactivity of the spots identified as DCVA was determined by liquid scintillation counting.

The results show an average of 78% recovered on day 0, 88% on day 139 of storage, and 80% on day 194 of storage of spiked soybeans.

For spiked dried vines, the comparable recoveries were 81%, 100%, and 91%.

These results appear to indicate that residues of the cyfluthrin metabolite DCVA do not degrade during the frozen storage of soybeans and dried soybean vines over a 194 day period.

In addition the petitioner cites other studies (EPA MRID #'s 410016-08, 424330-02, 424330-04, and 427104-02) that include data indicating the storage stability of cyfluthrin and in its metabolites over long term storage (up to 35 months) for numerous and varied crops.

Comment and Conclusion

The analytical methodology is adequate for enforcement purposes and for obtaining field trial data.

In regard to the storage stability of soybean rac's, the study submitted with this petition is irrelevant as the cyfluthrin metabolite DCVA is not regulated. (For guidance on how to conduct these studies the petitioner is referred to: Pesticide Reregistration Rejection Rate Analysis: Residue Chemistry: Follow-Up Guidance for Generating Storage Stability Data. EPA Document 737-R-93 February, 1993.)

However, other studies include data indicating that cyfluthrin and in its metabolites are relatively stable over long term frozen storage (up to 35 months) in/on numerous other crops.

Magnitude of the Residue in Plants

Residue Trials

Soybeans

The petitioner has submitted a total of 17 field trial studies in support of the requested tolerances in/on soybean rac's. Five of the studies are new and were conducted recently; twelve were previously submitted as part of PP#9F3731.

In the earlier studies, field trials were conducted in Arkansas, Georgia, Illinois, Indiana, Kansas, Mississippi, Nebraska, and Tennessee. Four foliar applications were made at 8-21 day intervals at a rate of 0.044 lbs. ai/A for a total of 0.176 lbs. PHI's were 14-30 days for soybean forage and hay and 31 - 76 days for beans and straw. Samples were stored frozen for up to 299 days prior to analyses.

The maximum residues of cyfluthrin found in these trials were: forage, 3.3 ppm; hay, 0.96 ppm; beans, 0.02 ppm; and straw, 0.49 ppm.

In its review (H. Fonouni, memo, 11/17/89) CBTS concluded: that additional data would be needed from another major soybean producing state (Minnesota was suggested); that a soybean processing study was needed; and that submitted storage stability studies were inadequate for the times of storage of samples in these trials. Consequently, CBTS recommended against the proposed soybean tolerances of PP#9F3731

The petitioner has now submitted 5 additional soybean residue trials. In these studies, field trials were conducted in Georgia, Iowa (2), Kansas, and Mississippi. (The petitioner notes that Iowa adjoins Minnesota, the state suggested in CBTS's review.) Four foliar applications were made at 6-8 day intervals at a rate of 0.7 oz. formulation /A for a total of 2.8 oz. [The petitioner's submission (Miles Report 103823 MRID 42864603) is in error in describing the rate as 0.7 oz ai/A. The application rate is equivalent to 0.175 oz ai/A or 0.044 lbs ai/A.] PHI's after the last application were 8-15 days for soybean forage and hay and 45-54 days for beans and straw. Samples were stored frozen for up to 440 days prior to analyses.

The maximum residues of cyfluthrin found in these trials were: forage, 1.3 ppm; hay, 3.2 ppm; beans, <0.01 ppm; and straw, 2.66 ppm.

Based on the combined data of all 17 trials, for this petition the petitioner proposes tolerances of 10 ppm on green forage; 1.5 ppm on dried hay; and 0.03 ppm on seed. No tolerances are requested for dried vines (straw) as this is no longer considered a rac by the Agency.

Soybean Processed Commodities

The petitioner has not submitted any additional information regarding residues in processed soybean commodities but again requests a feed additive tolerance of 0.1 for soybean hulls. A similar request was made as part of PP#9F3731/9H5574 and was recommended against in CBTS's review of that petition due to a lack of actual data for processed soybean commodities (H. Fonouni, memo, 11/17/89).

However, the petitioner cites by reference a study (Miles report 98502 MRID 410016-19) that was submitted as part of PP#9F3731. In that study, concentration factors experimentally determined for cottonseed processed commodities were applied to soybean processed commodities. Using this procedure, the petitioner deduced that tolerances of 0.1 ppm would be needed for soybean hulls and crude oil and a that tolerance of 0.05 ppm would be needed for refined

soy oil. The petitioner did request a feed additive tolerance for soybean hulls, but did not request tolerances for the meal and crude oil. As noted above the request for the tolerance on hulls was rejected by CBTS as it considered the procedure inappropriate. CBTS requested actual soybean processing data be provided.

Soybean Rac's and Processed Commodities Storage Stability Studies.

The petitioner has not supplied storage stability study data for soybean rac's or processed commodities stored for the length of time in these and the previously reported field trials. Instead it has submitted an earlier report (Miles Report 87104) of a study conducted in 1984 (see above) with a shorter period of storage and cites storage stability studies in Miles report 99631 that indicate that soybeans, soybean vines, and soybean leaves stored 1895, 1890, and 2512 days, respectively, lost 8, 11, or 28% of the residues, respectively. Miles takes these results as evidence that there would be no significant decrease in cyfluthrin residues in soybean rac's during the maximum storage interval of 433 days in the submitted studies.

Comments and Conclusions

The field trial residue data and the processing study procedure for arriving at residue levels in/on processed soybean commodities do not support the establishment of the requested tolerances for soybean rac's and processed commodities for the following reasons:

a) Although there are now a sufficient number and adequate geographic representation of soybean residue trials, the results cannot be reconciled with the requested tolerances. The maximum residue found on soybean forage was 3.3 ppm yet the requested tolerance is 10 ppm, a 3 fold difference; and even though the maximum residue found on soybean hay was 3.2 ppm the petitioner has proposed a tolerance of 1.5 ppm, half the actual maximum residue.

b) Soybean rac samples were stored for a maximum of 433 days in all of the submitted field trials, yet the storage stability study that the petitioner has submitted with this petition in response for additional data, maintained samples in storage for a maximum of 194 days and, as such, is not appropriate.

In addition, the petitioner cites Miles report 99631 that indicates that soybeans, soybean vines, and soybean leaves stored 1895, 1890, and 2512 days, respectively, lost 8, 11, or 28% of the residues, respectively.

Moreover, storage stability studies with various other crops and processed commodities when examined in toto demonstrate a lack of substantial degradation over the storage interval of samples of this soy bean field trial.

We conclude that it is unlikely that the sample storage interval of the soybean residue trials would have any significant effect on the residue levels found.

c) The procedure used to arrive at values for residues and tolerances for processed soybean commodities is inappropriate. The petitioner has not provided an actual soybean processing study but instead relies upon results of a cottonseed processing study.

We conclude that the petitioner needs to: a) request tolerances that reflect actual residue trial results, and b) conduct an actual soybean processing study.

Alfalfa

The petitioner provided residue data from 5 field trials conducted under label instructions (0.7 oz/ai/A per application up to 4; 0 day PHI) for alfalfa forage and hay. The maximum residue values for cyfluthrin were 3.76 ppm for forage and 8.85 ppm for alfalfa hay. Samples were stored for 479 days prior to analyses.

CBTS (H. Fonouni, memo, 11/17/89) requested: a) additional geographic representation in the field trials (Wisconsin or Minnesota were suggested); b) storage stability data for alfalfa samples stored 479 days; and c) data for alfalfa seed and alfalfa seed screenings if cyfluthrin were to be applied to alfalfa grown for seed or a definite proscription of this use.

The petitioner has responded to this request by submitting data from 3 additional field trials with alfalfa grown for forage and one trial with alfalfa grown for seed. The alfalfa grown for forage trials were conducted in California (2), and Nebraska. Cyfluthrin was applied by air at a rate of 0.05 lbs ai /A (1.14 x) once per cutting; samples of forage and hay were taken at 7, 14, and 21 days post application. The alfalfa grown for seed trials were conducted in California. Cyfluthrin was applied by air twice at a rate of 0.1 lbs ai /A (4 x the label rate). Samples of seed and chaff were obtained 13 days after the last application.

Samples of the alfalfa rac's were taken in July and August of 1989 and analyzed in October, November and December of 1990. The maximum time of storage is given as 479 days.

The maximum residues found in these trials were:

alfalfa forage	1.27 ppm at day 7
alfalfa hay	4.34 ppm at day 7
alfalfa seed	0.01 ppm at day 13
alfalfa chaff	8.40 ppm at day 13

Based on these and the previous results the petitioner proposed tolerances of:

alfalfa forage	5	ppm
alfalfa hay	10	ppm
alfalfa seed	0.02	ppm

No tolerance is proposed for alfalfa threshing chaff as this is not a feed item.

Comments and Conclusions

The results of the additional residue trials with alfalfa forage and hay do not support the requested tolerances as samples were taken 7 days after the last application while the label allows for a 0 day PHI. Only one trial was conducted to support a tolerance request for alfalfa grown for seed; one trial is an insufficient number to support a tolerance. No additional storage stability data for alfalfa rac's have been provided.

CBTS concludes that the alfalfa residue data currently available do not support the requested tolerances on alfalfa forage, hay, and alfalfa seed.

The petitioner should conduct additional trials on forage and hay in geographical diverse areas to increase the number of acceptable trials to at least twelve. (See EPA document 738-K-94-001 for guidance in determining the number and location of domestic crop field trials.) Additional data will also be needed for alfalfa grown for seed and for alfalfa seed screenings.

Sunflowers

CBTS' review of PP#9F3731 noted that field trial results supported the requested tolerance of 0.02 in/on sunflower seeds and 1.0 in/on sunflower forage. However, actual data was not supplied for processed sunflower commodities, the petitioner relying instead upon concentration factors derived from cottonseed processing studies. CBTS found this to be inadequate and required actual data from processing studies conducted with cyfluthrin-treated sunflowers.

In addition, the CBTS review cited the lack of specific storage stability data for the sunflower rac's (H. Fonouni, memo, 11/17/89).

The petitioner has responded to these defects by submitting a processing study and by citing previous studies indicative of the stability of cyfluthrin in other stored commodities.

Sunflower Seed Processing Study

Sunflower plants grown at Miles Research Park, Stilwell, KS, were treated with 3 individual foliar applications of cyfluthrin as Baythroid 2 EC at a rate of 3.5 oz ai/A, 5 x the suggested label rate. Applications were made at weekly intervals and sunflower seed were harvested 30 days after the last application. Samples were frozen immediately and shipped as such to the Food Protein Center of Texas A&M University at Bryan, Texas. Here samples of treated and untreated sunflower seeds were processed into hulls, meal, crude oil, and refined oil. Samples of the processed commodities and samples of seed were sent to Ricerca, Inc., Painesville, Ohio, for analysis of cyfluthrin residues. A maximum interval of 433 days elapsed between the harvest of samples and the last analysis.

The analytical procedure was that described in Miles Report 85823 which is the basis for the validated enforcement method available in PAM II for cyfluthrin residues. The procedure was slightly modified to deal with sunflower seed rac's. Method recoveries with the various matrices are given as 70 to 104%. The report limit of determination for seed is reported as 0.01 ppm and that for the processed commodities is given as 0.08 ppm. These values are the apparent residue values found when untreated seed and processed commodities were carried through the analytical procedure.

Results

The results of the analyses for cyfluthrin residues in seed and processed commodities, the concentration factor and the proposed tolerances are given in the following table.

Matrix	Residue* (ppm)	Concentration Factor	Proposed Tolerance (ppm)
Seed	0.16	-----	0.02**
Hulls	0.18	1.1	0.05
Meal	<0.08	<1	-----
Crude Oil	0.36	2.3	0.02
Refined Oil	0.17	1.1	0.05

* Cyfluthrin + DCVA at the 5 x rate

** Derived from 1 x rate

Storage Stability of Sunflower Rac's and Processed Commodities

The petitioner has not supplied storage stability study data for sunflower rac's or processed commodities as such but rather cites storage stability studies conducted with other crops.

Miles report 99631 indicates that soybeans, soybean vines, and soybean leaves stored 1895, 1890, and 2512 days, respectively, lost 8, 11, or 28% of the residues, respectively. Miles report 103821 cites a loss of 6% over 201 days for corn grain, 36% for rice grain

over 207 days, 20% for corn oil over 206 days, and 13% for rice hulls over 207 days. Miles takes these results as evidence that there would be no significant decrease in cyfluthrin residues in sunflower rac's or sunflower processed commodities during the storage interval of 433 days in the submitted study.

Comments and Conclusions

CBTS accepts the results of the sunflower seed processing study as adequate but considers the proposed tolerances derived from the study as inappropriate. The concentration factor of 1.1 found for sunflower refined oil and hulls is not significant and consequently food/feed additive tolerances for these commodities are not necessary. Although concentration was observed in crude oil, FAT's are not set on the crude oil. A revised Section F is needed.

Sunflower rac's and processed commodities were stored a maximum of 440 days considering this study and the previously submitted report of field trials conducted with sunflower rac's. The petitioner has not submitted any data for stored samples of sunflower rac's or processed commodities. However, the storage stability studies with various crops and processed commodities when examined in toto demonstrate a lack of substantial degradation over the interval of storage of the field trial and processing study. It is unlikely that the storage intervals of this study would have had any significant effect on the residue levels found.

CBTS can recommend for the sunflower rac tolerance if the food/feed tolerances are deleted.

Sweet Corn

The petitioner proposed tolerances for sweet corn rac's (forage, kernels, cobs, husks, and fodder) and sweet corn cannery waste (cobs plus husk) and provided field trial data to support the requested tolerances in PP#9F3731. The tolerances that were requested were: sweet corn 0.05 ppm; sweet corn forage 54 ppm; sweet corn cannery waste 1.4 ppm.

CBTS accepted the residue data as adequate to support the tolerances on sweet corn (defined as sum of residues on kernels plus that on cobs) and on cannery waste, but concluded that the maximum value for sweet corn forage (53.7 ppm) was an aberration and discarded it. The highest residue accepted for sweet corn forage was 13.6 ppm. (H. Fonouni, memo, 11/17/89).

However, CBTS did not recommend for tolerances of cyfluthrin on sweet corn due to the lack of storage stability data for sweet corn rac's. CBTS requested the petitioner to provide such data.

Instead the petitioner has submitted the results of 3 additional sweet corn field trials and has resubmitted its original request

for sweet corn tolerances minus the tolerance for cannery wastes as proposed in PP#9F3731.

In these trials conducted in 1989 in Oregon, Minnesota, and New York, 10 aerial applications were made at a rate of 50 grams ai/Hectare. Samples were stored a maximum of 298 days prior to analyses. Samples harvested immediately after the last application (0 day PHI) had maximum residues of 7.73 ppm in/on forage, <0.01 ppm in/on kernels, <0.01 ppm in/on cobs, and 1.79 ppm in/on cannery waste. These results do not affect the tolerances as originally proposed. No data was provided for sweet corn fodder in the current submission. The previous maximum value was 28.4 ppm.

Comments and Conclusions:

The petitioner has not responded to the specific deficiency cited in CBTS' review, i.e., the lack of storage stability data for corn rac's. The petitioner has not submitted any data for stored samples of sweet corn rac's or processed commodities. In its current submissions regarding other commodities (see above), the petitioner has cited Miles reports regarding the storage stability of cyfluthrin in various commodities. Among them are report 99631 which indicates a 2% decline in residues stored 783 days in corn green forage and report 103821 which indicates a decline of 6% in corn grain stored 201 days.

The storage stability studies with various crops and processed commodities when examined in toto demonstrate a lack of substantial degradation over the interval of storage of the field trial and processing study. It is unlikely that the storage interval would have had any significant effect on the residue levels found. Therefore, CBTS is willing to forego the issue of the storage stability of cyfluthrin in the specific crop sweet corn.

With respect to corn forage, upon examination of the field trial data, we consider the 53.7 ppm value to be aberrant. A tolerance of 15 ppm should be proposed. The sweet corn tolerance should be in terms of kernel plus cob with husk removed (K+CWHR). In addition, a tolerance of 30 ppm is needed for sweet corn fodder.

Magnitude of the Residue in Animals.

Animal tissue tolerances of 0.05 ppm for meat, fat, and meat by-products and for 0.01 ppm for milk are established as a result of the registered use on cotton. (40CFR180.436) The commodities for which tolerances are proposed in this petition can be a substantial part of animal diets. In this section we will determine the maximum dietary burden of cyfluthrin that could be resent in animal feed if the proposed tolerances are established by considering the rac's with the greatest proposed tolerances and the largest percentages of the diet. We will then consider if revisions would

be needed in the current secondary tolerances for livestock commodities.

Commodity	Dry Matter	Proposed Tolerance (ppm)	Max. % in Diet	Dietary Burden (ppm)
Alfalfa				
Forage/silage	35%	5	75	11
Hay	89	10	70	8
Soybeans				
Forage	35%	10	70	20
Sweet corn				
Forage	48%	54	50	47
		15	7.5	16

If we do not consider the proposed tolerance of 54 ppm for sweet corn forage (we consider this an aberrant value as noted above), the maximum dietary burden would be 20 ppm from the proposed tolerance on soybean forage.

Based on the feeding studies discussed in CBTS' reviews of petitions 4G2976 (R. Loranger, memo, 2/23/84) and 4F3046 (K. Arne, memo, 2/14/85) a dietary burden of 20 ppm would result in 0.73 ppm in ruminant fat, 0.02 ppm in ruminant muscle, and 0.08 ppm in milk. Residues would not be detectable in kidney and liver.

From these results, it is evident that the establishment of the tolerances proposed in this petition would result in the need for increases in the tolerances for secondary residues in animal commodities, at least for fat of cattle, goats, hogs, horses, and sheep.

Once the issue of the adequacy of the tolerances proposed for the commodities in this petition is resolved, the petitioner will need to propose adequate tolerances for secondary residues in animal commodities.

cc: Circ., R.F.; Garbus; PP#'s 3F4309/3H5686
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